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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,952	07/25/2000	Edna Chosack	S02/11	4168

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EXAMINER

SAADAT, CAMERON

ART UNIT

PAPER NUMBER

3713

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/600,952

Applicant(s)

CHOSACK ET AL.

Examiner

Cameron Saadat

Art Unit

3713

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 21-26 and 39-44 is/are rejected.
- 7) ☒ Claim(s) 18-20, 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

In response to Amendment filed on 8/21/02, Claims 1-27 and newly added claims 39-44 are pending. Claims 28-38 have been cancelled.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Regarding claim 4, the antecedent basis for "said texture mapping data" has not been clearly set forth.
3. Regarding claim 43, the antecedent basis for "said endoscopic cable" has not been clearly set forth.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 1-6, 11-17, 21, 23-25, 39-40, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobus et al. (U.S. Patent No. 5,769,640) in view of Gillio (U.S. Patent No. 5,882,206).**

Regarding claim 1, Jacobus et al. discloses a simulated medical procedure comprising: a simulated organ (column 7, lines 4-9; column 10, line 27), a simulated instrument 134 (column 7, lines 55-56), and simulated instrument locator 46. Jacobus et al. further teaches a visual display for displaying images created from actual data of an actual medical procedure, according to location of a simulated instrument within a simulated organ (column 4, lines 31-38). The display further includes a mathematical model for modeling the simulated organ according to a corresponding actual organ (column 7, lines 5-6); said model is divided into a plurality of segments and the display further includes a loader for selecting at least one of said plurality of segments for display, according to the location of the simulated instrument 134, and displayer 56 for displaying the simulated image. Jacobus et al. further discloses: a three-dimensional graphics generator 52 for generation of three-dimensional images of simulated instrument 134 (column 5, lines 28-31); three-dimensional graphics and display methods (see abstract). It is not explicitly disclosed that the mathematical model of the simulated organ is three-dimensional. However, Gillio teaches a virtual surgery system wherein a three-dimensional simulated organ is old and well known (column 1, lines 39-41). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the mathematical model of the simulated organ described by Jacobus et al., providing a three-dimensional model. The motivation for doing so would have been to

provide an accurate simulation of medical procedures (see Jacobus et al., column 3, lines 49-57).

In addition, Jacobus does not explicitly disclose that the plurality of segments are arranged in a linear sequence. However, the examiner takes official notice that this is an inherent feature. Furthermore, it is the applicant's admission that "the movement of a medical instrument through an organ *can only be linear* for a medical procedure; " the medical instrument *must* move through each portion of the organ in a linear sequence" (P.8 of amendment). In accordance, Jacobus et al. discloses that image data is provided and arranged based on the position and orientation "movement" of the simulated instrument (column 5, lines 20-22); which according to applicant, said movement "*can only be linear*", thus rendering this feature inherent.

Regarding claims 2-4, and 44, Jacobus et al. discloses a visual displayer 56, image database 42 and graphics overlay engine 54 (as per claim 2); a database 42 comprising animation of random movements of simulated instrument and random movement of simulated organ (as per claim 3), wherein the data includes images obtained from performing an actual medical procedure on an actual subject (as per claim 4) (see column 4, lines 39-49). Jacobus et al. does not explicitly disclose a texture mapping database. However, Gillio teaches database 104 comprising texture data (column 4, lines 63-66), wherein simulated images are overlaid with texture mapping data before being displayed (column 12, lines 64-65). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the database described by Jacobus et al., providing texture mapping data. The motivation for doing so would have been to provide a more realistic simulation and greater accuracy.

Regarding claim 5, Jacobus et al. teaches a system in which the images are obtained by recording visual data during a medical procedure and selecting said images from the recorded visual data (column 5, lines 24-31).

Regarding claims 6 and 40 Jacobus et al. discloses a mathematical model that features a plurality of polygons constructed according to a spline that determines the geometry of the mathematical model in three-dimensions (column 5, lines 24-31)

Regarding claim 10, Jacobus et al. teaches the use of a controller for selection of images, according to movement of a simulated instrument within a simulated organ. Jacobus et al. does not specifically teach the use of a controller that selects images according to at least one previous movement. However, Gillio discloses image selection according to one previous movement of a simulated instrument within a simulated organ (column 14, lines 14-17). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the controller for selection of images described by Jacobus et al., providing image selection at according to at least one previous movement. The motivation for doing so would have been to provide real-time, accurate visual feedback.

Regarding claims 11-12, Jacobus et al. discloses the use of a displayer, but does not explicitly teach the use of a graphical user interface (as per claim 11) and does not teach a graphical user interface that displays tutorial information (as per claim 12). However, Gillio teaches the use of a graphical user interface (column 5, lines 27-31), and also a graphical user interface that displays tutorial information (column 3, lines 8-11). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the Jacobus displayer with the graphical user interface and tutorial information,

thereby allowing a student to easily interact with the simulator and receive helpful information regarding the medical procedure.

Regarding claims 13-14, Jacobus et al. discloses a simulated organ (column 10, line 27) but does not specify the organ as being a gastro-intestinal tract (as per claim 13). However, it is disclosed that the simulated medical procedure comprises an endoscopic procedure. Furthermore, it is disclosed that the simulated model of the organ comprises data representing semi-flexible and smooth characteristics (column 10, lines 45-49). It is not explicitly stated that the simulated organ is constructed of semi-flexible material (as per claim 14). However, Gillio teaches a simulated organ as being a gastro-intestinal tract (column 7, lines 39-43). Furthermore, Gillio teaches a simulated organ 110 comprising virtual orifice 112, and wherein the surface of the orifice is adjusted (column 7, lines 29-31; column 6, lines 64-66) with springs and rollers pressing against the orifice wall. Although it is not explicitly stated it is inherent that the orifice must be flexible in order to be functional. The orifice wall must be flexible thereby permitting adjustment of the orifice size using the pressure of springs and rollers as shown in Figure 4. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the simulated organ described by Jacobus et al., providing a simulated organ of a gastro-intestinal tract and constructing it from smooth, semi-flexible material. The motivation for doing so would have been to provide an appropriate simulated organ for the endoscopic simulated procedure described by Jacobus et al. while providing accurate and realistic tactile feedback from the simulated organ.

Regarding claim 15, Jacobus et al. discloses a simulated instrument 48 comprising a sensor for determining the location of the simulated instrument within the simulated

organ, and a computer 44 to provide visual feedback of the simulated instrument location (column 5, lines 11-19). Regarding claim 16, Jacobus et al. further discloses tactile feedback mechanism 46/48 corresponding to the location of the simulated instrument. Although it is not explicitly stated that the simulated instrument is an endoscope, Jacobus et al. does disclose that the simulation may be an endoscopic medical procedure (column 3, line 57). It is the examiner's position that it is old and well known to use an endoscope for an endoscopic medical procedure.

Furthermore, although Jacobus et al. does not expressly disclose that the location sensor is positioned at the tip of the endoscope (as per claim 16), it is the examiner's position that positioning a location sensor at the tip of an endoscope is old and well known. Hence, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the position of the location sensor of the endoscope described by Jacobus et al., and positioning it on the tip of the endoscope because it is critical for a trainee or surgeon to be aware of the location of the tip of the endoscope with respect to a patient's organ, to prevent damage, and to guide the instrument within the organ.

Regarding claim 17, Jacobus et al. discloses a force reflective mechanism 140 that provides tactical feedback on the simulated instrument with servo-motors, but does not specifically teach that the mechanism is contained in a gastro-intestinal tract. However, Gillio teaches a tactile feedback mechanism located in the gastro-intestinal tract comprising servo-motors, wherein the rollers 230, 232, 234, and 236 can be fitted with the servo-motors to contact the semi-flexible material of the orifice 112 of the simulated organ 110; a controller for controlling the servo-motors, such that the position of the rollers is determined by the controller in order to provide tactile feedback (column 7,

lines 12-20). Although a piston is not specified, it is the examiner's position that it would have been an obvious matter of choice well within the capabilities of one skilled in the art to use a piston in place of the rollers described by Gillio because this feature provides no criticality with respect to the invention. Thus, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the simulated organ tactile feedback mechanism described by Jacobus. et al., providing tactile feedback contained in a gastro-intestinal track. The motivation for doing so would have been to provide a simulated organ with an adjustable orifice to simulate various types of organs (see Gillio, column 7, lines 29-36).

Regarding claim 21, Jacobus et al. discloses a simulated organ tract that is substantially a straight tube, such that the tactile feedback and visual feedback are substantially independent of a geometrical shape of the simulated organ tract (see Fig. 9, ref. 136).

Regarding claim 23-25, Jacobus et al. teaches a simulated endoscopic procedure, however does not explicitly disclose an endoscope that comprises a tool unit. However, Gillio teaches a simulated endoscope comprising a tool unit further comprising simulated forceps, and a channel within the handle for receiving the simulated forceps; a tool control unit in communication with a computer for detecting movement of the simulated forceps and providing visual (as per claim 24) and tactile feedback (column 14, line 66 – column 15, line 34). Thus, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the endoscopic simulation described by Jacobus et al., providing a simulated endoscope comprising a tool unit. The motivation for doing so would have been to provide a more realistic simulation and to provide

standard, well known components of an endoscope. Furthermore, Gillio teaches that the control unit detects the motion of simulated forceps (column 20, lines 60-65), but does not specify a detection of a roll (as per claim 25). However, the examiner takes official notice that the feature of detecting up, down, and "roll" movement of a tool within an endoscope is old and well known.

Regarding to claim 39, Jacobus et al. discloses that a loader stores segments of the organ model in real-time (column 4, lines 10-13). The examiner takes official notice that the use of RAM is old and well known.

7. Claims 7 -9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobus et al. (U.S. Patent No. 5,769,640) in view of Gillio (U.S. Patent No. 5,882,206), further in view of Asano et al. (U.S. Patent No. 5,956,040).

Jacobus et al. discloses a mathematical model of a simulated organ, but does not specify a deformation in the simulated organ determined by altering a function (as per claim 7) and adding polygons to a portion of the function (as per claim 8). It is further not specified that the simulated organ is modeled as a straight line that can be altered through a function (as per claim 9). Asano et al., however teaches a deformation in the simulated organ determined by altering a function (column 4, lines 21-41). It is further taught that the simulated organ is modeled as a straight line that can be altered through a function (column 4, lines 21-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to alter the Jacobus et al. simulated organ model by providing graphical enhancements taught by Asano et al., thereby providing accurate visual representation of the simulated organ

8. **Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobus et al. (U.S. Patent No. 5,769,640) in view of Gillio (U.S. Patent No. 5,882,206), further in view of Rosenberg (U.S. Patent No. 5,767,839).**

Jacobus et al. discloses a tactile feedback mechanism that is operated according to tactile feedback obtained during a medical procedure on an actual subject (column 4, lines 39-49), but does not specify that the tactile feedback is obtained through virtual reality gloves. However, Rosenberg teaches a tactile feedback mechanism that incorporates virtual reality gloves (column 1, line 26). Hence, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide tactile feedback through virtual reality gloves to provide simulated feedback for a surgical procedure.

9. **Claims 26, 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobus et al. (U.S. Patent No. 5,769,640) in view of Gillio (U.S. Patent No. 5,882,206), further in view of Ishikawa et al. (U.S. Patent No. 6,071,233).**

Jacobus et al. discloses a simulated endoscopic procedure, but does not specify a specific type, such as a polypectomy (as per claim 26). However, the examiner takes official notice that it would have been an obvious matter of choice well within the capabilities of one skilled in the art to provide a specific type of endoscopic procedure. Furthermore, Jacobus et al. does not explicitly disclose that visual feedback of a "simulated loop" is provided (as per claims 26, 40-42). However, Ishikawa et al. teaches an endoscope 1 wherein loop 33 is in direct view of optical observation system 9. At the time of the invention, since the simulated images are captured from a real endoscopic procedure, it would have been obvious to a person of ordinary skill in the art to modify

the endoscopic simulation described by Jacobus et al., providing visual feedback of loop 33 as taught by Ishikawa et al. thereby allowing simulation of loop excision surgical procedures.

Allowable Subject Matter

10. Claims 18-20, and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art does not fairly suggest:

- As per claim 18, a guiding sleeve connected to the tip on an endoscope comprising a ball bearing for rolling along an inner surface of a gastrointestinal tract; and wherein a linear motor is attached to the guiding sleeve for providing tactile feedback by contacting the inner surface of the gastrointestinal tract.
- As per claim 19, a tactile feedback mechanism comprising a plurality of inflatable rings surrounding an endoscope.
- As per claim 27, a light wheel for alternately blocking and unblocking light according to movement of simulated forceps; using a light detector to determine the movement of the simulated forceps.

Response to Arguments

11. Applicant's arguments with respect to claims 1-6, 7, 9, 10-17, and 21-26 have been considered but are moot in view of the new ground(s) of rejection. Therefore, this action is made NON-FINAL.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cameron Saadat whose telephone number is 703-305-5490. The examiner can normally be reached on M-F 8:00 - 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Valencia Martin-Wallace can be reached on 703-308-4119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

CS
October 30, 2002



S. THOMAS HUGHES
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